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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/645,715 | 08/20/2003 | George V. Guittard | AR02366USACON3 | 8447 |
| 27777 | 7590 | 09/19/2005 | | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER GEORGE, KONATA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,715

Applicant(s)

GUITTARD ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 40-48 are pending in this application.

Petition to Correct Inventorship

1. In view of the papers filed July 12, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding the names Suneel Gupta and Gayatri Sathyan.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Finality of Previous Office Action

2. The finality of the rejection of the last Office action is withdrawn.

Action Summary

3. Examiner acknowledges the cancellation of claims 32-39. Therefore, any and all objections and/or rejections directed towards them are hereby withdrawn.

4. The rejection of claims 40 and 48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US 5,840,754

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is hereby withdrawn as applicant has timely filed a terminal disclaimer to overcome rejection.

5. The rejection of claims 40 and 44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-21 of US 6,124,355 is hereby withdrawn as applicant has timely filed a terminal disclaimer to overcome rejection.

6. The rejection of claims 40-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 5 of US 6,262,155 is hereby withdrawn as applicant has timely filed a terminal disclaimer to overcome rejection.

7. The rejection of claim 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending application number 09/785,805 is hereby withdrawn as applicant has timely filed a terminal disclaimer to overcome rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 40, 41, 44, 45 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Rantala (WO 96/12477).

Rantala discloses in Figures 1 and 2 a “substantially” constant plasma concentration of oxybutynin for 24 hours from peroral dose one 10 mg controlled release tablet. The relatively constant plasma concentration for 24 hours is evidence that oxybutynin must have been released at a substantially zero order rate of release over a 24 hour period. See also claims 16-17. Tables 2 and 4 on pages 8 and 9 teach that the oxybutynin is administered with an hydrochloride salt. Since the treated condition includes neurogenic bladder (e.g. urine leakage or incontinence), applicant’s “management of incontinence” is met. It is also taught on page 5, lines 25-26 and 36-37 that the composition is in the form of tablets and the composition can further contain agents or additives such as alkyl celluloses.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 42, 43, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rantala (WO 96/12477) as applied to claims 40, 41, 44, 45 and 48 in view of Enomoto et al. (JP 406009388A).

Rantala discloses in Figures 1 and 2 a “substantially” constant plasma concentration of oxybutynin for 24 hours from peroral dose one 10 mg controlled

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release tablet. The relatively constant plasma concentration for 24 hours is evidence that oxybutynin must have been released at a substantially zero order rate of release over a 24 hour period. See also claims 16-17. Tables 2 and 4 on pages 8 and 9 teach that the oxybutynin is administered with an hydrochloride salt. Since the treated condition includes neurogenic bladder (e.g. urine leakage or incontinence), applicant's "management of incontinence" is met. It is also taught on page 5, lines 25-26 and 36-37 that the composition is in the form of tablets and the composition can further contain agents or additives such as alkyl celluloses. The prior art does not teach the specific alkyl cellulose as claimed by applicant.

Enomoto et al. discloses a sustained release of oxybutynin hydrochloride together with a gel-forming substance such as hydroxypropyl methylcellulose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Enomoto which teaches hydroxypropyl methylcellulose as a gel-forming substance with oxybutynin hydrochloride in the invention of Rantala. The expected result would be an oxybutynin hydrochloride composition with hydroxypropyl methylcellulose having a zero order rate of release over a 24-hour period.

Conclusion

10. Claims 40-48 are rejected.

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Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

Alton Pryor
Alton Pryor
Primary Examiner
A.U. 1616